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| APPLICATION NO.          | FILING DATE         | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |
|--------------------------|---------------------|----------------------|-------------------------|------------------|
| 10/500,882 07/07/2004    |                     | Yoshito Kuroda       | 0216-0510PUS1           | 8742             |
| 2292                     | 292 7590 12/23/2005 |                      | EXAMINER                |                  |
|                          | WART KOLASCH &      | BIRCH                | PUTTLITZ, KARL J        |                  |
| PO BOX 747<br>FALLS CHUI | RCH, VA 22040-0747  |                      | ART UNIT                | PAPER NUMBER     |
| ,                        |                     |                      | 1621                    |                  |
|                          |                     |                      | DATE MAILED: 12/23/2005 |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

|  | Application No.  | Applicant(s)                    |  |  |  |  |
|--|--|---------------------------------|--|--|--|--|
|  | 10/500,882   | KURODA ET AL.                   |  |  |  |  |
| Office Action Summary  | Examiner   | Art Unit                        |  |  |  |  |
|  | Karl J. Puttlitz   | 1621                            |  |  |  |  |
| The MAILING DATE of this communication app<br>Period for Reply   | ears on the cover sheet with the c   | orrespondence address           |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |  |                                 |  |  |  |  |
| Status   |  |                                 |  |  |  |  |
| 1) Responsive to communication(s) filed on <u>07 Ju</u>  | ılv 2004.  |                                 |  |  |  |  |
| <u> </u>   | action is non-final.   |                                 |  |  |  |  |
| 3) Since this application is in condition for allowar  |  | secution as to the ments is     |  |  |  |  |
| closed in accordance with the practice under E   |  |                                 |  |  |  |  |
| Disposition of Claims  |  |                                 |  |  |  |  |
| 4) Claim(s) <u>1-5</u> is/are pending in the application.  |  | ·                               |  |  |  |  |
| 4a) Of the above claim(s) is/are withdraw  | vn from consideration.   |                                 |  |  |  |  |
| 5) Claim(s) is/are allowed.  |  |                                 |  |  |  |  |
| 6)⊠ Claim(s) <u>1-5</u> is/are rejected.   |  |                                 |  |  |  |  |
| 7) Claim(s) is/are objected to.  |  | •                               |  |  |  |  |
| 8) Claim(s) are subject to restriction and/or  | r election requirement.  |                                 |  |  |  |  |
| Application Papers   |  |                                 |  |  |  |  |
| 9) The specification is objected to by the Examiner.   |  |                                 |  |  |  |  |
| , ==   |  | Examiner.                       |  |  |  |  |
|  | ne drawing(s) filed on is/are: a)  accepted or b)  objected to by the Examiner.  Soplicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). |                                 |  |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).   |  |                                 |  |  |  |  |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.   |  |                                 |  |  |  |  |
| Priority under 35 U.S.C. § 119   | •  |                                 |  |  |  |  |
| <ul> <li>12) Acknowledgment is made of a claim for foreign</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents</li> <li>2. Certified copies of the priority documents</li> <li>3. Copies of the certified copies of the priori application from the International Bureau</li> <li>* See the attached detailed Office action for a list</li> </ul>   | s have been received.<br>s have been received in Application<br>ity documents have been receive<br>u (PCT Rule 17.2(a)).   | on No ed in this National Stage |  |  |  |  |
| Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date  | 4)  Interview Summary<br>Paper No(s)/Mail Da<br>5)  Notice of Informal P<br>6)  Other:   |                                 |  |  |  |  |

#### **DETAILED ACTION**

## Information Disclosure Statement

The information disclosure statement filed 7/7/2004 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. Note: copies of the Japanese references are missing from the PTO's electronic copy of the captioned application.

## Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1recites the steps of depositing glycolic acid crystals from an aqueous glycolic acid solution and separating the deposited crystals from the glycolic acid solution. It is unclear how "depositing", as set forth on pages 36-45, is different from a separating step, since the broadest reasonable interpretation of "separating", can

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necessarily include depositing of glycolic acid crystals. Clarification, by way explanation, or amendment, is required.

## **Prior Art Rejections**

The claims of the application are drawn to, inter alia, a method for producing high purity glycolic acid crystals from an aqueous glycolic acid solution, which comprises the steps of: (1) providing an aqueous glycolic acid solution (A) containing monomeric glycolic acid and a glycolic acid condensation product, said aqueous glycolic acid solution (A) having the following characteristics (a), (b) and (c): (a) a water content of from 5 to 20% by weight, (b) a calculated monomeric glycolic acid weight ratio of from 0.60 to 1.00, said calculated monomeric glycolic acid weight ratio being defined as a ratio of the total weight of said monomeric glycolic acid and said glycolic acid condensation product to the weight of said aqueous solution (A), wherein the weight of said glycolic acid condensation product, and (c) a monomeric glycolic acid content of from 20 to 57% by weight, (2) depositing glycolic acid crystals from said aqueous glycolic acid solution (A).

The claims cover other embodiments comprising deposition of glycolic acid crystals from said aqueous glycolic acid solution (A) in said step (2) is performed at a temperature in the range of from -30 to 50C.

The claims cover other embodiments comprising deposition of glycolic acid crystals from said aqueous glycolic acid solution (A) in said step (2) is performed in the

The claims cover other embodiments comprising washing the separated glycolic acid crystals with an aqueous glycolic acid solution (B).

Also, the claims cover embodiments specifying the aqueous glycolic acid solution (B).

## Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

presence of glycolic acid crystals as seed crystals.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 92/05138 (WO 138).

WO 138 teaches a glycolic acid product of a carbonylation reaction given as the tables on pages 3 and 4:

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| The final product is a 70% technical-      | -àtage adneona |
|--|----------------|
| solution; a typical analysis of this mater |                |
| total acid as HAA (wt. %)                  | 71.34          |
| free acid as HAA (wt. %)                   | 62.49          |
| formic acid (wt. %)                        | 0.24%          |
| color (Gardner)                            | · 3            |
| chloride (ppm)                             | 2.6            |
| iron (ppm)                                 | 0.2            |
|  | •              |
| EAA (wt. %)                                | 62,4           |
| RAA dimer (wt. t)                          | 8.6            |
| diglycolic acid (wt. %)                    | 2.2            |
| methoxyacetic acid (wt. 4)                 | 2.2            |
| formic sold (wt. 4)                        | n 94           |

A seeded crystallization of glycolic acid crystals in the glycolic acid solution is given on pages 5 and 6, at a preferred temperature of 5°C.

The foregoing anticipates the rejected claims within the meaning of section 102.

## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 138 in view of Applicant's Admission.

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Claims 4 and 5 cover those embodiments comprising washing the separated glycolic acid crystals with an aqueous glycolic acid solution (B) and the claims cover embodiments specifying the aqueous glycolic acid solution (B). WO 138 fails to explicitly teach these embodiments. However, Applicant's admit that sweating the crystals is a conventional process in the art (see page 52 of the specification), and, moreover, those of ordinary skill would expect, absent evidence to the contrary that a sweating solution in a glycolic acid process would comprise an aqueous glycolic acid solution within the parameters set forth in claim 5. Therefore, washing the separated glycolic acid crystals with an aqueous glycolic acid solution (B) and those embodiments specifying the aqueous glycolic acid solution (B) are well within the motivation of those of ordinary skill, and therefore, prima facie obvious.

#### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karl J. Puttlitz whose telephone number is (571) 272-0645. The examiner can normally be reached on Monday to Friday from 9 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter, can be reached at telephone number (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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